

## Allergen Control for Food Processors



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Discuss the Fundamentals of  
Food Allergens

Review the Regulatory Landscape

Assist in the Development of  
an Allergen Control Plan




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### Presentation Outline

- Background
- Regulatory Considerations
- What Can You Do?
- Allergen Control Plan
- Key Elements of Control
- Complaint Handling
- What now?
- Resources

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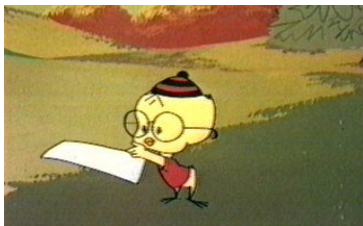
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## Allergen Awareness Exercise



Write down the contents of your last meal.

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## Background

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## Food Allergy Facts and Statistics

- Food Allergen – immunologic response that involves IgE antibodies
- Food Intolerance/Hypersensitivity – adverse response to food limited to gastrointestinal problems
- Symptoms Range and Vary – hives, swelling, respiratory complications, anaphylaxis

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## Food Allergy Facts and Statistics

- There is **no cure** for food allergies.
- The best approach is to **avoid the food allergen**.
- Steroids, antihistamines, asthma medications, epinephrine **may treat some symptoms**.

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## Food Allergy Facts and Statistics

- Food Allergy is a growing public health concern.
- Between 1997 and 2007, there was an **18%** increase in the number of children with food allergies (CDC, 2008).
- The prevalence of peanut allergy among children **tripled** between 1997 and 2008.
- There are **8 food allergens** that account for **90%** of all food-allergic reactions.

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## Common Food Hypersensitivities

- Strawberries
- Sulfites
- FD&C Yellow #5
- MSG (monosodium glutamate)
- Lactose
- **Gluten**

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## Gluten?



- Proposed Rule 1/2007, Final Rule 8/2013
- Defines term “Gluten Free” and similar terms
- Establishes 20 PPM threshold
- Use of term is voluntary, threshold is not
- More information at: [FDA.gov](http://FDA.gov) - search “gluten free”

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## Why Increased Attention to Allergens?

- Increased awareness – consumers and industry
- Improved detection methods (ELISA, PCR, etc)
- Trend toward value-added products
- Negative publicity; financial impact; regulatory actions
- Severe adverse reactions

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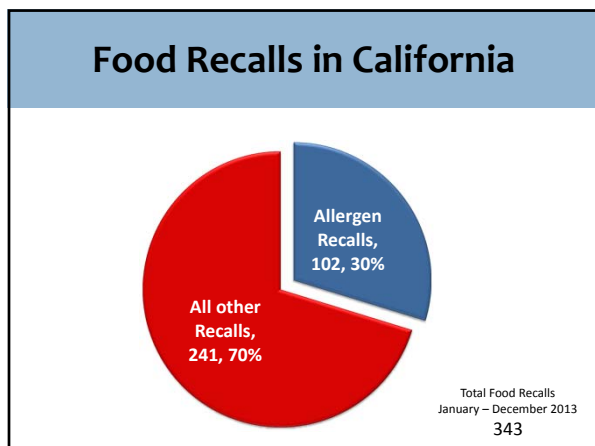
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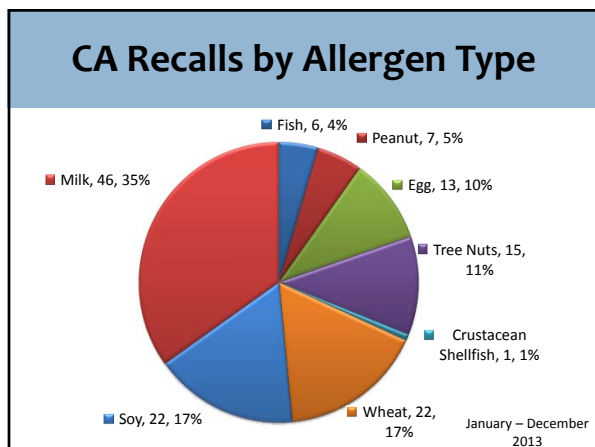
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### Impacts?

Increase in Food Recalls

Economic/Financial

Reputation

**Public Health**

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**News Reports**



**Colton Meade, 2011**  
**Natalie Giorgi, 2013**

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**Regulatory Considerations**

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**Which Laws/Regulations Apply?**



- FALCPA
- Sherman Food, Drug and Cosmetic Law
- 21 CFR Part 110
- 21 CFR Part 101

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## Compliance and Enforcement



State and federal law deem food that is not properly labeled to be misbranded.

### Misbranded food can lead to:

- ▣ Notice of Violation
- ▣ Embargo
- ▣ Recall
- ▣ Fines and Penalty

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## Allergen Labeling Law: FALCPA

The Federal Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) was signed into law on 8/2/2004.

- Food labels must list the food source names of all ingredients that contain any protein derived from the **eight major food allergens**.
- FALCPA labeling requirements became effective on January 1, 2006.
- Pursuant to California Health and Safety Code section 110100, FALCPA is adopted as California law.

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## FALCPA Requirements

Food facilities are required to:

1. Comply with practices to reduce or eliminate cross-contact of a food with residues of major food allergens that are not intentional ingredients of the food.
2. Ensure that major food allergens are properly labeled on foods.

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## What are the Major Food Allergens?

- Milk
- Eggs
- Fish
- Crustacean shellfish (e.g., crab, lobster, shrimp)
- Tree nuts (e.g., almonds, walnuts, pecans, coconuts)
- Peanuts
- Wheat
- Soybeans

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## FALCPA Exemptions

**FALCPA law does not apply to:**

- Highly refined oils
- Raw agricultural commodities

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## FALCPA Exemptions

- Food ingredient exempt under a **petition or notification** process
  - Petition standard: "... does not cause an allergic response that poses a risk to human health."
  - Notification standard: "... does not contain allergenic protein."
  - Scientific evidence must be provided for FDA's review.

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## Allergen Food Label

The name of the food source of a major food allergen must appear in **one of two ways**:

- In parentheses following the name of the ingredient  
e.g., lecithin (soy), flour (wheat), and whey (milk)
- Immediately after or next to the list of ingredients in a "Contains" statement  
e.g., "Contains Wheat, Milk, and Soy"

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## Unrequired Label Statements?

- "May contain..."
- "Produced in facility which also manufactures..."
- "Manufactured on shared equipment..."

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## Flavors, Coloring and Incidental Additives

A flavoring, coloring or incidental additive that contains a major food allergen is subject to FALCPA labeling requirements.

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## Allergen Awareness Exercise

- ❑ Did your last meal include any of the eight major food allergens? If yes, which one(s)?

- ❑ Milk
- ❑ Eggs
- ❑ Fish (e.g., bass flounder, cod, etc.)
- ❑ Crustacean Shellfish (e.g., crab, lobster, shrimp)
- ❑ Tree nuts (e.g., almonds, walnuts, pecans, coconuts)
- ❑ Peanuts
- ❑ Wheat
- ❑ Soy




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## FSMA : Proposed Rule on Preventive Controls Released

**FDA U.S. Food and Drug Administration**  
Protecting and Promoting Your Health

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

**Food**  
Home Food Food Safety Food Safety Modernization Act (FSMA)

**Food Safety**  
Food Safety Modernization Act (FSMA)  
About FSMA  
Full Text of the Law  
Implementation & Progress  
Dockets Open for Comment  
Meetings, Hearings, and Workshops  
Press Releases  
Speeches, Statements, and Other Correspondence  
Presentations & Print Material  
Videos, Webinars, and Interviews  
Alliances  
Frequently Asked Questions  
Translations of New FSMA

**Fact Sheet on the FSMA Proposed Rule for Preventive Controls for Human Food: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**  
Updated January 14, 2013

Preventive Standards under the FSMA Main Page

View the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Proposed Rule. Docket number: FDA-2011-14-0800. Comments due by May 16, 2013.

See also:

- Preliminary Regulatory Impact Analysis
- **NOTE:** On January 4th, the Preventive Controls for Human Food proposed rule and its accompanying Preliminary Regulatory Impact Analysis (PRIA) statement were posted on this site. An incorrect version of the PRIA statement was posted. On January 15th, a corrected version of the PRIA statement was posted and is available in the docket folder, see FDA-2011-14-0800, as reference 194.
- Draft Qualitative Risk Assessment of Risk of Adulteration/Contaminations for Activities (Outside the Farm Definition) Conducted in a Facility Co-located on a Farm (PDF: 900KB)
- External Peer Review of the FDACFSMA Draft Qualitative Risk Assessment: Risk of Adulteration/Contaminations for Activities (Outside the Farm Definition) Conducted in a Facility Co-located on a Farm (PDF: 559KB)

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## Hazard Analysis and Risk Based Preventive Controls




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## Preventive Controls Required



- ☐ Process controls
- ☐ Food allergen controls
- ☐ Sanitation controls
- ☐ Recall plan

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## Interesting Fact



On June 8, 2010, the U.S. Department of Transportation issued a proposal to restrict peanuts on commercial airlines. Later, the agency withdrew the proposal citing federal law that indicates no federal money can be used to provide a peanut-free buffer zone or restrict the distribution of peanuts until 90 days after a peer-reviewed study is submitted to Congress.

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## Quiz

Which of the following contains a major food allergen as defined by **FALCPA**?

- A. Strawberries
- B. Wheat
- C. Gluten
- D. Casein

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## Quiz

A “may contain” statement can be used in lieu of **current Good Manufacturing Practices**.

True or False

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## Quiz

By documenting “**whey**” in the ingredient list of a product which contains whey, the manufacturer has met the requirements outlined in **FALCPA**.

True or False

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**What can YOU do?**

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## Steps for the Food Processor

Conduct an **Allergen Risk Assessment**.

What is Allergen Risk Assessment?

A process by which the causes of intentional and unintentional allergens in food production are identified.

Goal:

Minimize the possibility of allergen cross-contact in food.

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## Where Are Allergens From?

### □ Intentional Allergens

- Intentionally added for a specific purpose.



### □ Unintentional Allergens

- Inadvertently added through human error, cross-contact, or similar.

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## Allergen Mapping Puzzle




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## When Should A Risk Assessment Be Done?

Planning Stage

Any Changes

**Now!**

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## Allergen Control Plan

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## What is it?

An **Allergen Control Plan** is a written document that includes effective control measures used to minimize allergen cross-contamination and prevent misbranding via a failure to disclose allergens on the label.




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## How to Develop an Allergen Control Plan

- Assemble an Allergen Control Team
  - ▣ Define and assign staff roles and responsibilities
- Establish policies and procedures for allergen control
  - ▣ Seven Key Elements of Control
- Reassess the effectiveness of Allergen Control Plan
  - ▣ Audits

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## Allergen Control Team



- ▣ Research & Product Development
  - ▣ Management
  - ▣ Quality Assurance
- ▣ Purchasing/Distributing
  - ▣ Manufacturing
- ▣ Packaging/Labeling
  - ▣ Warehousing
- ▣ Regulatory Affairs
- ▣ Training Officer

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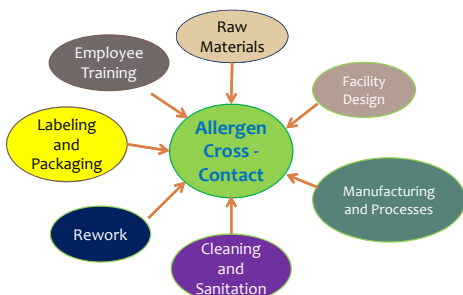
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## 7 Key Elements of Control




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## Allergen Control Plan



Evaluate Effectiveness  
Audit

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## Key Elements of Control

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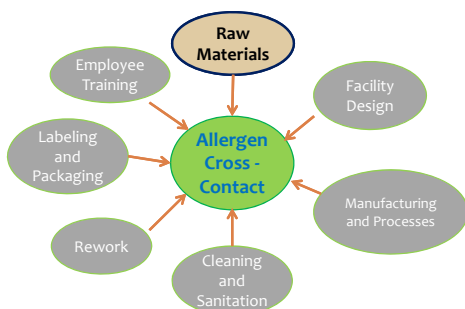
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## 7 Key Elements of Control




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## 1. Raw Materials

### 1. Receiving – establish specifications



- Audit **suppliers and co-packers** to ensure compliance with Allergen Control Plan
- Request **Certificates of Analyses (COA)** or **Certificates of Guarantees (COG)** for incoming ingredients
- Verify ingredients against **Bills of Lading, Purchase Orders, or Specifications**

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## 1. Raw Materials

### 2. Inspection

- Review the **labels** of incoming ingredients for the Big 8 food allergens.
- Clearly mark or tag incoming allergenic ingredients using **color-codes, labels or symbols** to reduce mix-ups and cross-contact.
- Develop a **plan** to handle damaged containers, accidental spills, or misuse of allergenic ingredients.




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## 1. Raw Materials

### 3. Storage

- Store allergenic ingredients in clearly identified areas or boxes using color-coded labels.




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## 1. Raw Materials

### 3. Storage

Segregate allergenic raw ingredients in a manner to minimize cross-contamination using the following practices:

- Use dedicated pallets and bins
- Store allergenic ingredients on lower shelves
- Designate specific storage areas for specific type of allergens (e.g., "wheat only")
- Ensure containers are tightly sealed to avoid air-borne contamination

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## 7 Key Elements of Control




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## 2. Facility Design



- Traffic flow
- Ventilation/air filtration
- Staging and storage
- Processing lines
- Physical separation or barriers
- Space

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## 7 Key Elements of Control




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## 3. Manufacturing and Processes

### 1. Dedicate equipment and food contact surfaces (FCS)

- Segregate the production areas (conveyors, rooms and facilities) for in-process food with major food allergens




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## Dedicated Equipment and FCS




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## Dedicated Equipment and FCS

- Use color coding system
  - ▣ Ingredients
  - ▣ Equipment and utensils that contact allergens
- Create barriers to protect in-process food from cross-contamination via adjacent conveyors, carts or other food processing equipment.

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## 3. Manufacturing and Processes

### 2. Production scheduling

- ▣ Process food containing allergens longer to minimize changeovers
- ▣ Process food containing allergens at the end of the manufacturing run
- ▣ Process food containing allergens separately
- ▣ Schedule cleaning and sanitation between production to prevent cross-contamination of allergens and non-allergens

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## Which is the IDEAL Production Scheduling?

### Run A



Sugar Cookies



Chocolate Chip Cookies



Chocolate Chip + Peanut butter Cookies



### Run B



Sugar Cookies



Chocolate Chip + Peanut Butter Cookies



Chocolate Chip Cookies

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## 7 Key Elements of Control




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## 4. Cleaning and Sanitation

- Ensure equipment design allows for thorough cleaning, sanitizing and inspecting
  - ▣ Avoid dead legs that accumulate food
  - ▣ Clean in Place systems
- Follow Sanitation Standard Operating Procedures (SSOPs)
  - ▣ Clearly written procedures that are easy to follow
  - ▣ Define the scope and schedule for cleaning the equipment, food contact surfaces and the plant
  - ▣ Train employees on the cleaning procedures

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## 4. Cleaning and Sanitation

Use appropriate cleaning methods :

- |  |  |
|--|--|
| <b>1. Dry cleaning</b> <ul style="list-style-type: none"> <li>▪ wipe/brush</li> <li>▪ scrape</li> <li>▪ vacuum</li> <li>▪ blow down</li> <li>▪ compressed air</li> </ul> | <b>2. Wet Cleaning</b> <ul style="list-style-type: none"> <li>▪ rinse</li> <li>▪ high pressure water or steam</li> <li>▪ wash</li> <li>▪ sanitize</li> </ul> |
|--|--|

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## The Best Approach to Cleaning...

If you can't see it

If you can't reach it



**Then, YOU CAN'T CLEAN IT!!!**

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## 4. Cleaning and Sanitation

- Verify sanitary practices through frequent visual inspections
  - ▢ Define the scope of verification procedures
- Validate cleaning with analytical methods, via the ELISA test kits
  - ▢ Define the intention and scope of validation
- Document and review cleaning and sanitizing records
  - ▢ Keep detailed records for cleaning, verification and validation
  - ▢ Evaluate the allergen cleaning program annually for effectiveness

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## 7 Key Elements of Control




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## 5. Rework

- **Clearly label rework**
  - ▢ Use color tags, containers, plastic liners or bar coding to document and track reworked product
- **Use same ingredients or formulation in the reworked products**
  - ▢ Check specifications for allergens
  - ▢ If rework product calls for reformulation, use the CORRECT labels

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## 5. Rework

- Ensure that shared or re-feed systems are **adequately cleaned**
  - ▢ Equipment, grinders, food contact surfaces and other shared equipment
- Document rework to allow for **proper identification and traceability**
  - ▢ Rework plan and controls
  - ▢ Uses for reworked products
  - ▢ Usage records




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## 7 Key Elements of Control




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## Top 3 Reasons for Undeclared Allergens

**Labeling**

60%

**Processor**

20%

**Supplier**

20%




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## 6. Labeling and Packaging

- 21 CFR Part 101 – Food Labeling
- FALCPA requirements
- Label Control

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## 6. Labeling and Packaging

- Implement a tracking system that includes:



- Lot coding or Lot numbering
- BIUB

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## Words of Caution!!!



### Advisory labeling

- does not replace the firm's responsibility to prevent allergen cross-contact
- should not be used as a "catch all" statement
- should only be used to describe the potential presence of unintentional allergen after a complete risk-assessment

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## 6. Labeling and Packaging

**ALLERGY INFORMATION:**  
Consumers with food allergies or other sensitivities, please review the ingredients carefully.

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## 7 Key Elements of Control




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## 7. Employee Training




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## 7. Employee Training

### Curriculum should include:

- ❑ Top 8 Food Allergens
- ❑ Basics of Food Safety (cGMPs, SSOP, HACCP)
- ❑ Policies and procedures for allergen control
- ❑ Strategies to reduce cross- contamination
  - Color-coding
  - Proximity of equipment
  - Production Scheduling
  - Cleaning/Sanitizing
  - Labeling
  - Rework procedures

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## 7. Employee Training

### *Training and communication are key to effective allergen control*

Management is responsible for the following:

- ❑ Ensuring **allergen control** policies and procedures are readily available for employees.
- ❑ Ensuring employees are aware of **changes** to allergen control plan.
- ❑ Documenting allergen awareness **trainings**.
- ❑ Posting of **signage** for use in dedicated areas to minimize the potential for cross-contamination.
- ❑ Creating an environment where employees can **report problems** observed.

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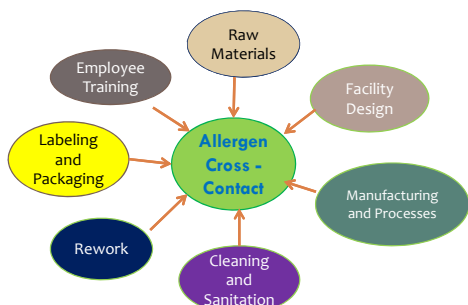
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## Allergen Control: Review




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## Group Training Exercise - Scenario

- Scenario – “Yummy Yuckies”
- Break into 7 small groups (Key Elements)
- Assign roles to team members (note-taker, facilitator and presenter)
- Begin discussion (15 minutes)
- Present and share with the class (10 minutes)

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## Group Training Exercise - Outcomes

1. Identify three causes.
2. How could you have prevented them?
3. What are you implementing?




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## How Do We Know There Is A Problem?



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## Complaint Handling

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## Allergen Complaints

Customer service response should include training staff on how to handle complaints.

**Step 1: Create a complaint record**

**Step 2: Initiate an investigation**

**Step 3: Evaluate processes and controls**

**Step 4: Develop corrective actions to achieve complaint resolution**

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## Allergen Complaints

### Step 1 – Develop a Complaint Log

- List complainant's Name and Contact Information.
- Describe the incident including date and time, nature of complaint, symptoms of illness, etc.
- Identify product: purchase date and lot code.
- Sample Log - <http://www.cdph.ca.gov/pubsforms/Documents/fdbRIgde04.pdf>

Anonymous complaints are VERY difficult to substantiate.

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PRODUCT COMPLAINT REPORT																																													
<input type="checkbox"/> Allergic (No Rx) <input type="checkbox"/> Injury <input type="checkbox"/> Product Spoilage <input type="checkbox"/> Container Integrity <input type="checkbox"/> Foreign Object Miscellaneous: <input type="checkbox"/> Other <input type="checkbox"/> Taste <input type="checkbox"/> Color <input type="checkbox"/> Other								Report No: _____																																					
Product: _____																																													
Complainant Taken By: _____				Date: _____		Time: _____																																							
Complainant Name: _____																																													
Company: _____																																													
Address: _____																																													
City: _____ State: _____ Zip: _____ Country of Residence: _____																																													
Product: Brand: _____ Size: _____																																													
Code/Expiration Date: UPC: _____ Product sold: <input type="checkbox"/> Shelf Stable <input type="checkbox"/> Refrigerated <input type="checkbox"/> Frozen																																													
Description of Problem (for Allergic see below): _____																																													
Purchase Location: _____ Purchase Date and Time: _____																																													
Address: _____ City: _____ State: _____ Phone: _____																																													
Product Handling: Storage: _____ Preparation: _____																																													
<table border="1"> <thead> <tr> <th>Name</th> <th>Age</th> <th>Symptoms in order of appearance</th> <th>Time</th> <th>Medical Treatment Necessary</th> <th>Diagnosis/Lab Confirmation</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>										Name	Age	Symptoms in order of appearance	Time	Medical Treatment Necessary	Diagnosis/Lab Confirmation																														
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GI Distress = Vomiting • Nausea H = Headache D = Diarrhea F = Fever B = Burning It = Rash/Itches Medical Provider Name: _____ Address: _____ Phone: _____ How much (if any) consumed? _____ Product Remaining: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unopened packages _____ Location of Remaining Product: _____ How is Product Stored: _____ Health Department Notification: <input type="checkbox"/> No <input type="checkbox"/> Yes Department: _____																																													

### Complaint Intake Form

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## Allergen Complaints

### Sample Tracking Log

Date	Complainant Name and Contact Information	Product Name	Complaint Description	Staff	Investigation Notes	Status	Corrective Action
1/1/2012	John Smith (000) 000-000; not reachable from 8:00 am - 12 noon	ABC Product	Complainant alleges undeclared allergen in ABC product, reporting food made me sick. Complainant reports shortly after eating ABC product, his skin broke out in hives for three days.	QA Manager (or other appropriate staff)	Spoke with complainant on 1/2/12. Complainant reports has allergy to peanuts. Complainant alleges experienced allergic reaction to ABC food product. Met with complainant on 1/4/12 to obtain sample product. Sent to lab for analysis on 1/6/12. Report came back positive for peanut residue on 1/13/12.	Report to manager submitted on 1/14/12. Food Recall issued on 1/14/12	Allergen training provided on 1/20/12

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## Allergen Complaints

### Step 2 – Initiate an Investigation

Complaints may reveal problems with the following:

- Failure to List All Ingredients
- Labeling Mistakes or Omissions
- Lapse in Sanitation Controls
- New Supplier Infiltration
- Raw Materials/Ready-to-Eat Food Separation
- Product Identification Numbers/Lot Codes

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## Allergen Complaints

### Step 3 – Evaluate Processes and Controls

Allergens need to be managed from start to finish in the production process to ensure effective controls.

Review current policies and procedures to confirm that products manufactured and/or distributed meet quality control and safety standards.

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## Allergen Complaints

### Step 4 – Develop Corrective Actions to Correct the Problem.

- Fix labeling errors
- Ways to prevent unintentional cross-contamination
  - ▣ retraining staff
  - ▣ more equipment
  - ▣ change of production schedule
  - ▣ other

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## What Now?

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## Issue Recall Notice/Press Release



Recall Notice  
Press Release

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## Recall Coordinators

- ▣ **State:** CDPH-FDB – send email to:  
[FDBeru@cdph.ca.gov](mailto:FDBeru@cdph.ca.gov)
- ▣ **Federal:** U.S. FDA - list of regional recall coordinators can be found at:  
<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm>

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- Food and Drug Branch

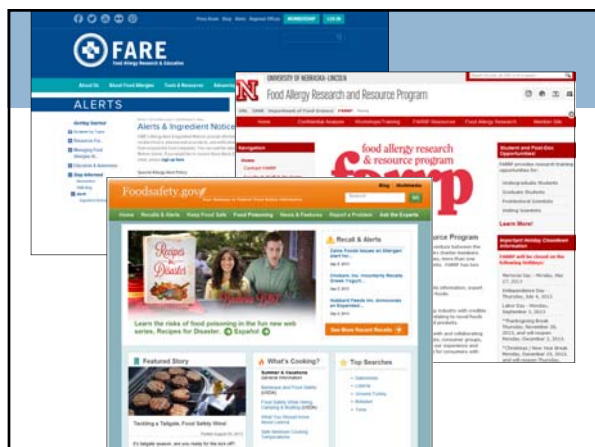
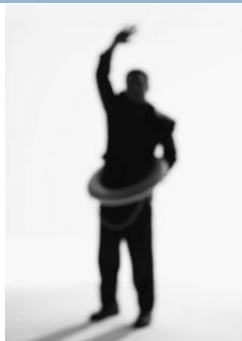
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- **Food and Drug Branch**
  - Top 8 Food Allergens & Their Common Aliases
  - Allergen Scorecard
  - [CDPH.CA.GOV/FDB](http://CDPH.CA.GOV/FDB)
- **Additional Information**
  - [FoodAllergy.org](http://FoodAllergy.org)
  - [FoodSafety.gov](http://FoodSafety.gov)
  - University Nebraska - Lincoln
  - [FDA.gov](http://FDA.gov)



## FDA Recall Reports

The FDA webpage on Recalls, Safety Alerts and Market Withdrawals illustrates many cases of product recalls due to undeclared allergen ingredients.

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<http://www.fda.gov/Safety/Recalls/default.htm>

## FDA Industry Guidance

**FDA industry guidance includes:**

- [Food Allergens Labeling](#)
- [Guidance, Compliance & Regulatory Information](#)
- ["Dear Colleague" Letter About the "Food Allergen Partnership"](#)
- [Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food](#)
- [FDA Allergy Warning Letter](#)
- [Food Allergen Awareness: An FDA Priority](#)
- [Food Allergen Labeling and Consumer Protection Act of 2004 \(Public Law 108-282, Title II\)](#)




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- ✓ **Discuss the Fundamentals of Food Allergens**
- ✓ **Review the Regulatory Landscape**
- ✓ **Assist in the Development of an Allergen Control Plan**

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## Questions




**CDPH-Food and Drug Branch**  
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Sacramento, CA 95899-7435

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Training Questions –  
[FDBTraining@cdph.ca.gov](mailto:FDBTraining@cdph.ca.gov)

General Questions –  
[FDBInfo@cdph.ca.gov](mailto:FDBInfo@cdph.ca.gov)

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